

wherein said expression regulatory sequences comprise 5' regulatory sequences selected from the group consisting of an uromodulin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene and an aquaporin gene.

76. (New) The method of claim 75, further comprising:

- (c) collecting said urine containing said protein or peptide from said mammal; and
- (d) separating said protein or peptide from said urine.

77. (New) The method of claim 75, wherein said 5' regulatory sequence comprises a uromodulin promoter.

78. (New) The method of claim 77, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

79. (New) The method of claim 78, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

80. (New) The method of claim 79, wherein said 3' regulatory sequences are selected from the group consisting of an uromodulin gene, an uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene and an aquaporin gene.

81. (New) The method of claim 75, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

82. (New) The method of claim 81, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

83. (New) The method of claim 82, wherein said 3' regulatory sequences are selected from the group consisting of an uromodulin gene, an uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, an osteopontin gene, an urinary kallikrein gene,

an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene and an aquaporin gene.

84. (New) The method of claim 75, wherein said protein or peptide is an enzyme or an enzyme inhibitor.

85. (New) The method of claim 84, wherein said enzyme is a protease, a glycosyltransferase, a phosphorylase, a kinase or a γ -carboxylase.

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86. (New) The method of claim 75, wherein said protein or peptide is selected from the group consisting of prothrombin, Factor VII, Factor IX, Protein C, Protein S, Factor V, Factor VIII, α 1-anti-trypsin, antithrombin III, fibrinogen, albumin, an immunoglobulin, a hormone, a growth factor, erythropoietin, a bone morphogenetic protein and an ion channel protein.

87. (New) The method of claim 75, wherein said transgenic mammal is a pig, sheep, goat, cow, rodent, rabbit or horse.

88. (New) A non-human transgenic mammal that produces in its urine a protein or peptide, wherein said transgenic mammal has stably integrated into its genome an exogenous gene encoding a protein or peptide comprising expression regulatory sequences operably linked to said exogenous gene, wherein said expression regulatory sequences comprise 5' regulatory sequences selected from the group consisting of an uromodulin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene and an aquaporin gene, and wherein said protein or peptide is detectable in the urine of said transgenic mammal.

89. (New) The mammal of claim 88, further comprising:

- (c) collecting said urine containing said protein or peptide from said mammal; and
- (d) separating said protein or peptide from said urine.

90. (New) The mammal of claim 88, wherein said 5' regulatory sequence comprises a uromodulin promoter.

91. (New) The mammal of claim 90, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

92. (New) The mammal of claim 91, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

93. (New) The mammal of claim 92, wherein said 3' regulatory sequences are selected from the group consisting of an uromodulin gene, an uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene and an aquaporin gene.

94. (New) The mammal of claim 88, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

95. (New) The mammal of claim 94, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

96. (New) The mammal of claim 95, wherein said 3' regulatory sequences are selected from the group consisting of a uromodulin gene, a uroplakin gene, a renin gene, a erythropoietin gene, an apolipoprotein E gene, an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, a uropontin gene, a nephrocalcin gene and a aquaporin gene.

97. (New) The mammal of claim 88, wherein said protein or peptide is an enzyme or an enzyme inhibitor.

98. (New) The mammal of claim 97, wherein said enzyme is a protease, a glycosyltransferase, a phosphorylase, a kinase or a γ -carboxylase.